

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2001 list were published in the Federal Register in February 2001.

New Approvals

ANADA Number: 200-281

Pioneer Product: 139-191
Trade Name: WormexxTM Flavored Tablets
Ingredients: Pyrantel pamoate
Sponsor: Blue Ridge Pharmaceuticals, Inc.
Approval Date: January 3, 2001
Status: Over-the-counter
Route: Oral
Species: Dogs
Drug Form: Tablets (flavored)
Concentration: 22.7 and 113.5 milligrams per tablet
Indications:

21CFR 520.2041(b)

Suitability Petition Action

Number: 01P-0045/CP1
Sponsor: Bimeda, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, lincomycin hydrochloride and spectinomycin dihydrochloride pentahydrate, which differs from the pioneer product, Pharmacia & Upjohn Co.'s NADA 046-109 by the following characteristics: The generic product will provide for a product containing spectinomycin dihydrochloride pentahydrate whereas the pioneer product contains spectinomycin sulfate tetrahydrate.
Action: Filed on January 26, 2001

Number: 01P-0066/CP1
Sponsor: First Priority, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, ivermectin/pyrantel, which differs from the pioneer product, HeartgardTM Plus (ivermectin/pyrantel), Merial Limited's NADA 140-971 by the following characteristic: Ivermectin/pyrantel generic is a compressed chewable tablet and HeartgardTM Plus is an 'extruded' chewable tablet.
Action: Filed on February 6, 2001

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